

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Sangui262-04	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/013575	International filing date (day/month/year) 30.11.2004	Priority date (day/month/year) 26.12.2003
International Patent Classification (IPC) or national classification and IPC A61L15/28, A61L15/32, A61L15/38, A61L15/40		
Applicant SANGUIBIO TECH GMBH		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.	
2.	This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.	
3.	This report is also accompanied by ANNEXES, comprising:	
a.	<input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:	
	<input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).	
	<input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.	
b.	<input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).	
4.	This report contains indications relating to the following items:	
	<input checked="" type="checkbox"/> Box No. I	Basis of the report
	<input type="checkbox"/> Box No. II	Priority
	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
	<input type="checkbox"/> Box No. IV	Lack of unity of invention
	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<input type="checkbox"/> Box No. VI	Certain documents cited
	<input type="checkbox"/> Box No. VII	Certain defects in the international application
	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-31 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-30 _____ received by this Authority on 12.04.2006 with letter
- nos.* _____ received by this Authority on of 12.04.2006
- ☒ the drawings:
- sheets 1-3 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70:2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-30	YES
	Claims	NO
Inventive step (IS)	Claims 1-30	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-30	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

This report makes reference to the following documents:

- D1: EP-A-1 118 705 (GUNZE CO., LTD; NAKAMURA, KENJI; NAKAGAWA, MOMOKI), 25 July 2001 (2001-07-25)
- D2: DE 197 12 699 A1 (THÜRINGISCHES INSTITUT FÜR TEXTIL- UND KUNSTSTOFF-FORSCHUNG E.V., 07), 1 October 1998 (1998-10-01)
- D3: EP-A-0 049 177 (LABORATOIRES D'HYGIENE ET DE DIETETIQUE L.H.D., SOCIETE ANONYME DITE), 7 April 1982 (1982-04-07)

I) Novelty (PCT Article 33(1) and 33(2))

The present application meets the requirements of PCT Article 33(1) for novelty because the subject matter of claims 1-30 is novel within the meaning of PCT Article 33(2).

Document D1 discloses a pad or knitted fabric as a medical product for use on the skin, as a protection against or prevention of dry or itchy skin, for example in dermatitis, eczema and skin irritation (see claim 18).

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
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The pad is treated with a solution which contains amino acids, peptides and glucosamine (chitosan).

The following amino acids are mentioned: arginine, glycine, proline and glutamic acid. D1 does not expressly mention a wound dressing, but it is conceivable that the pad ("woven fabric") disclosed in D1 can also be used for treating wounds, since a medical use is inherently mentioned in claim 18.

D1 thus differs from the subject matter of the invention in that only 2% protein hydrolysate are used, while according to the independent claims in the present application, a minimum content ranging from 19-56% must be present. Consequently, D1 is not prejudicial to the novelty of the subject matter of claims 1-30.

II) Inventive step (PCT Article 33(1) and 33(3))

Document D2 is regarded as the prior art closest to the subject matter of claims 1-30.

It discloses an adhesive wound dressing with wound-treating substances. The wound pad of the adhesive wound dressing comprises knitted or woven fabrics, non-wovens and/or gauze-cotton wool compresses. The polysaccharides contained in the wound pad preferably belong to the group of chitosans (cf. column 3, lines 5-16). The additives contained in the wound pad are: binders, thickeners, pharmaceutical active substances, anti-oxidising agents, carotene, etc... (cf. column 3, lines 55-65).

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The wound dressings according to D2 contain "conjugates of polysaccharides, such as chitosan, with proteins" (see claims 4 and 5 of D2).

The subject matter of claims 1-30 therefore differs from the disclosure of D2 in that neither polycarboxylic acids nor carboxylic acids are mentioned, and in that the protein proportion is not of at least 19%.

D2 should therefore not be considered prejudicial to the novelty of the subject matter of the present application (PCT Article 33(3)).

The prior art describes the use of mixtures of proteins and polysaccharides, but never cross-linked. As a result, only knitted fabrics containing this mixture are disclosed in the prior art.

The technical effect achieved is that of dispensing with a substrate in the wound dressings according to the invention.

In view of the cited prior art, it would not be obvious for a person skilled in the art that this type of wound dressing could be stable and effective, since mixtures of proteins with polysaccharides which are cross-linked do not necessarily remain homogeneous.

Consequently, the subject matter of claims 1-30 of the invention should be acknowledged to involve an inventive step in its entirety (PCT Article 33(1) and 33(3)).

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The application does not meet the requirements of PCT Article 6 because claims 1-30 are unclear.

Both the present description and the claims show such language shortcomings that contradictions and misunderstandings of their meaning and scope of protection of the claimed subject matter result.

1. "polycarboxylic acids":

The chemical term "polycarboxylic acids" designates carboxylic acids having more than one COOH group, such as dicarboxylic acids (malonic acid, fumaric acid, malic acid, succinic acid, glutamic acid (see claim 4), tricarboxylic acids (such as trimellitic acid) or tetracarboxylic acids (such as pyromellitic acid), etc.

The following so-called polycarboxylic acids (according to claim 4) are not actually polycarboxylic acids: lactic acid, ascorbic acid, salicylic acid, pyrrolidonic acid.

The applicant gives his own definition of polycarboxylic acids (see page 9, lines 1-7): "carboxylic acids which, in addition to a carboxylic group, contain another functional group (hydroxy, carboxy, amino group)".

This definition is inconsistent with the chemical definition and is not admissible.

2. "polyfunctional amino acids"

Polyfunctional amino acids, according to the applicant's

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Box No. VIII Certain observations on the international application

own definition, are amino acids which, "in addition to the amino and acid functionality, bear one or more additional functionalities".

According to claim 5, arginine, methionine, cysteine and N-acetylcysteine count among the polyfunctional amino acids.

Taurine is a 2-aminoethansulfonic acid, and hence not an amino acid in the conventional sense of the term.

Although glycine, alanine and proline are amino acids, they are not polyfunctionalised amino acids.

The scope of protection of dependent claim 5 is thus broader than that of the main claim. The description also supports "polyfunctional amino acids", to the extent that "polyfunctional amino acids lead to the stabilisation of quaternary structures of protein compounds".